NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS DEUTSCHLAND GMBH, AVENTIS PHARMA S.A., ABBOTT GMBH & CO. KG, ABBOTT LABORATORIES and ABBOTT LABORATORIES, INC., Plaintiffs, v. GLENMARK PHARMACEUTICALS INC., USA and GLENMARK PHARMACEUTICALS LTD, Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 07-CV-5855 (DMC-JAD)

DENNIS M. CAVANAUGH, U.S.D.J.

This matter comes before the Court upon motion by Defendants Glenmark Pharmaceuticals, Inc., USA and Glenmark Pharmaceuticals, Ltd. (collectively, "Defendants" or "Glenmark") as a renewed motion for judgment as a matter of law against Sanofi-Aventis Deutschland GMBH, Aventis Pharma S.A., Abbott GMBH & CO. KG, Abbott Laboratories and Abbott Laboratories, Inc. ("ALI") pursuant to FED. R. CIV. P. 50(b). No oral argument was heard, pursuant to FED. R. CIV. P. 78. After considering the submissions of all parties, it is the decision of this Court, for the reasons herein expressed, that Defendants' motion is **denied**.

I. BACKGROUND[1]

Glenmark filed a Rule 50(a) motion on January 13, 2011 arguing that the '244 patent is invalid for obviousness. (ECF No. 315). On January 14, 2011, the jury reached a verdict finding claim three of the '244 patent nonobvious, in favor of Plaintiffs. (Verdict Form, Jan. 14, 2011, ECF No. 319.) Glenmark contends that this Court failed to apply the appropriate standard to this issue in its September 30th Opinion, and that the jury verdict finding nonobviousness was not based upon substantial evidence. As such, Glenmark argues, they are entitled judgment as a matter of law that claim three of the '244 patent is invalid for obviousness.

Abbot Laboratories was granted an exclusive license, by Abbott Germany, to manufacture, use and sell pharmaceutical products containing trandolapril and verapamil hydrochloride.[2] Plaintiffs initiated suit against Defendants for patent infringement. (Opinion 2, June 30, 2011, ECF No. 369). Abbott Laboratories is the owner of New Drug Application ("NDA") No. 20-591, through which ALI sells drug products containing the trandolapril or verapamil hydrochloride combination in the United States under the trademark Tarka®.[3] Id. The Food and Drug Administration ("FDA") published a list entitled the "Approved Drug Products with Therapeutic Equivalence Evaluation" (also known as, the "Orange Book"), which is applicable to Abbott Laboratories' aforementioned NDA for Tarka® tablets. Id. at 3. That list includes the '244 patent, at issue in this case. Id.

[1]The information in this section is taken from the submissions of the respective parties as well as the Opinions of this Court on prior motions (ECF Nos. 74, 151, 156, 164, 342, 369, 378).

[2]The patent issued to inventors Reinhard Becker, et al. and was initially assigned to Hoechst Aktiengesellschaft, who subsequently assigned ownership rights to Aventis Pharma Deutschland GmbH, renamed Sanofi-Aventis Deutschland GmbH. Aventis Pharma S.A. had been granted an exclusive license to manufacture, use and sell pharmaceutical products containing trandolapril and verapamil hydrochloride, which it granted to Abbott Germany.

[3]Abbott Laboratories granted ALI an exclusive sub-license to use and sell pharmaceutical products containing trandolapril and verapamil.

The '244 patent, titled "Combination of Angiotensin-Converting Enzyme Inhibitors with Calcium Antagonists as well as their Use in Drugs" was issued on February 24, 1998. (Rosendorff Dec. Ex. 1, Aug. 14, 2009, ECF No. 45-2.) Glenmark contends, in its renewed motion for judgment as a matter of law, that claim three of the '244 patent is invalid because the claimed subject matter would have been obvious at the time it was invented. (Def.'s Mot. 1, Oct. 28, 2011, ECF No. 381.) Claim three of the patent covers pharmaceutical compositions of the ACE inhibitors trandolapril or quinapril with a calcium antagonist in an amount effective for treating hypertension, or high blood pressure. Id. at 3; see also Pl.'s Opp'n 6, Nov. 23, 2011, ECF No. 404. Glenmark contends that the prior art taught this exact concept, consequently ending the obviousness inquiry. (Def.'s Mot. 2-4).

II. STANDARD OF REVIEW

The Federal Circuit has held that judgment as a matter of law is appropriate only if the Court finds that "a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 841 (Fed. Cir. 2010). The question is whether the jury's verdict is sustainable on the evidence presented, not whether this Court would have gone another way. Rothman v. Target Corp., 556 F.3d 1310, 1317 (Fed. Cir. 2009). When the jury is supplied with sufficient valid factual information to support the verdict it reaches, that is the end of the matter. McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1355 (Fed. Cir. 2001). "In such an instance, the jury's factual conclusion may not be set aside by a [judgment as a matter of law]." Id. This Court is limited, on a motion under FED. R. CIV. P. 50(b), to reviewing the legal conclusions.

III. DISCUSSION

Plaintiffs contend that the Court applied the proper standard, engaged in a proper analysis, and that a large body of evidence supported the jury's verdict. (Pl.'s Opp'n 1-2, Nov. 23, 2011, ECF No. 404). Citing an inapposite case, Defendants attempt to characterize the proper standard of review on a renewed motion for judgment as a matter of law as more searching than it is, explaining that "substantial evidence" is required and that the Court is "to view all the evidence and the inferences reasonably drawn therefrom." Aloe Coal Co. v. Clark Equip. Co., 816 F.2d 110, 113 (3d Cir. 1987). Rather, the applicable standard, as noted prior, requires only that the jury verdict be supported by "sufficient evidence." FED. R. CIV. P. 50(a)(1); also Global-Tech Appliances, Inc. v. SEB S.A., 131 S.Ct. 2060, 2064 (2011) (holding "sufficient evidence" is the relevant standard when reviewing a judgment as a matter of law in a patent matter), and Rothman, 556 F.3d at 1316 (a motion for judgment as a matter of law may only be granted where a reasonable jury would not have a "legally sufficient" evidentiary basis to find for the non-moving party).

Defendants contend that claim three of the '244 patent is obvious and Plaintiffs merely combined elements in the prior art or, alternatively, that the combination itself existed in the prior art. (Def.'s Reply 1-4, Dec. 7, 2011, ECF No. 405). Plaintiffs persuasively counter that Defendants' argument fails to consider the specific values attached to the elements involved in the '244 patent. (Pl.'s Opp'n 9). Further, patent claim three cannot be devalued as just a substitution of one ACE inhibitor for another pre-existing in the prior art. Id. Rather, Plaintiffs presented sufficient evidence and persuaded a reasonable jury that claim three involved deliberate choices based on the benefits involved in trandolapril and quinapril over other ACE

inhibitors in the prior art. Id. at 10; Contra Def.'s Reply 3.

A. Obviousness

It is well established that an obviousness inquiry is dependent upon four factors, as set out in Graham v. John Deere Co.: 1) the scope and content of the prior art, 2) the level of ordinary skill in the art;[4] 3) the differences between the prior art and the claimed invention, and 4) any secondary indicia of non-obviousness. 383 U.S. 1, 17 (1966). The detailed differences between claim three and that existing in the prior art require a fact determination appropriate for presentation to a jury. Agrizap, Inc. v. Woodstream Corp., 520 F.3d 1337, 1341 (Fed. Cir. 2008) (it is not appropriate for the Court to weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version). The evidence and the inquiry indeed were presented to a jury, which concluded upon this issue on January 14, 2011.

Essentially, the Graham rule guides the parties to engage in a comparison of the invention to relevant inventions existing in the prior art. Defendants argue that they are entitled to judgment as a matter of law because Plaintiffs failed to compare claim three to the closest combination in the prior art. Plaintiffs contend no references teach or suggest trandolapril and quinapril in the prior art. (Pl.'s Opp'n 12). Defendants point to the '361 patent as a comparison, however, the '361 patent does not combine elements at the same specific values. Id. at 9. The comparison shows nothing but the fact that the general concept of combining an ACE inhibitor with a calcium antagonist existed in the prior art. Id. Further, other ACE inhibitors require a different dosing schedule, and one that is not viable, practical or effective. Id. at 12. Plaintiff's

[4] The parties agree that a person of ordinary skill in the art, in this matter, is a person with a high level of skill. (Def.'s Reply, Dec. 7, 2011, ECF No. 405). Plaintiffs contend and highlight the importance of noting this person is further knowledgeable in the area of chemistry. (Pl.'s Opp'n 16).

experts explained that among the unexpected advantages of trandolapril and quinapril combinations, was the longer duration of action resulting from the double ring structure. Id. at 14.

The jury verdict of nonobviousness of claim three was based on the foregoing sufficient evidence presented by Plaintiffs.

B. Secondary Considerations

The secondary considerations include commercial success and long felt but unsolved needs. Graham, 383 U.S. at 17; see also, Sjolund v. Musland, 847 F.2d 1573, 1582 (Fed. Cir. 1988). The parties also discuss, and this Court will address, any unexpected results stemming from the invention, as a secondary consideration to obviousness. See, In re De Blauwe, 736 F.2d 699, 705 (Fed. Cir. 1984).

1. Long-felt Need

The Court and jury are constrained to consider whether the claimed invention satisfies a long felt need, or solved problems where others had failed. Sjolund, 847 F.2d at 1582 (emphasis in original). Plaintiffs contend the claimed invention satisfies a long-felt need for longer duration hypertensive medication. (Pl.'s Opp'n 16). Further, Plaintiffs describe the need for hypertensive medication with fewer side effects. Id. Defendants acknowledge the shortfalls of hypertensive medication requiring multiple doses and exhibiting certain side effects. (Def.'s Mot. 10).

Plaintiffs submitted substantial evidence supporting the propositions that claim three itself provides for a medication that is longer acting and results in fewer side effects than those medications available prior. For support, Plaintiffs point to Dr. Carey's testimony that in 1986,

the state of hypertension treatment involved the long-standing problems of short duration action and the need to help blood vessels and kidneys, adding that the invention of claim three addressed those long-felt concerns. (Pl.'s Opp'n 17). It is clear from the evidence provided by Dr. Carey and others, regarding the tighter bind of either trandolapril or quinapril into ACE, that the extended release element is attributable to claim three rather than any other reason Defendants suggest. Contra Def.'s Reply 10-2. There is sufficient evidence upon which a reasonable jury could find this consideration weighed in favor of Plaintiffs.

2. Unexpected Results

The inquiry into whether the claimed invention exhibits unexpected results is a factual one, requiring a showing of superiority compared to results achieved with other articles. In re De Blauwe, 736 F.2d at 705 (citation omitted). Plaintiffs make the more extreme argument that none of specific benefits of Tarka® were recognized in the prior art. Plaintiff's buttress such a claim by showing results that could not have been known in the prior art, such as the duration of action, benefit to kidney structure, and function and lessening of side effects. (Pl.'s Opp'n 12.) The state of the art, Plaintiffs note, was not focused on combination drugs. Id. at 14. Even those combination drugs that existed were not a product of this same formula.

Further, the combination of components would not have been expected to yield such favorable results, Plaintiffs say. (Pl.'s Opp'n 13). The innovativeness of claim three, involves the concept that there was no reason to expect the double ring structure to be advantageous over the single ring structure. Id. at 12. The most logical to select would be those having single rings. Id. at 14. Plaintiffs mention that, of the array of ACE inhibitors, quinapril was obviously better than captopril. (Pl.'s Opp'n 8). However, other ACE inhibitors showed similar

advantages over captopril. Id. Plaintiffs explain "at least 297 ACE inhibitors were known to have as good or better ACE inhibition than captopril or enalapril according to testing in some biological assay, in a test tube, in an animal, or in humans." (Pl.'s Opp'n 14) (citation omitted). Plaintiffs convincingly argue that they made a deliberate choice based on their research to go with quinapril. Id. Sufficient evidence was presented for a reasonable jury to find this consideration weighed in favor of Plaintiffs.

3. Commercial success

The secondary consideration of commercial success involves a standard of "significant sales." Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1377 (Fed. Cir. 2000). Defendants argue that any commercial success Tarka® enjoyed had no nexus with the claimed invention itself, and resulted rather from an extensive and costly promotion and marketing campaign. (Def.'s Mot. 16-7). Plaintiffs counter that Tarka®'s sales were higher than competitors Lexxel and Teczum, which combined enalapril with calcium inhibitor combinations. (Pl.'s Opp'n 22). Defendants contend Plaintiffs made an enormous marketing effort which was necessary to generate even modest sales, and despite which, Plaintiffs still suffered a loss of almost $200 million on the sales of Tarka®. (Def.'s Mot. 17). Defendants contend that marketing ceased in 2007 and steadily fell thereafter. Id.

Plaintiffs counter that in 2009, Tarka® sales achieved $65 million and Tarka®'s peak sales reached $100 million despite stopping promotional efforts in 2006. (Pl.'s Opp'n 21). Further, Plaintiffs point to the fact that "Abbott paid $190 million to Sanofi-Aventis for rights to license the '244 patent and make and sell Tarka®." Id. Following the expiration of the '361 patent in 2007, Plaintiffs contend that rather than catalyzing a drop in sales as Defendants

suggest, Tarka®'s sales remained stable. Rather, sales began to drop at the entry of Glenmark's generic version of the drug into the market.[5]

Plaintiffs present sufficient evidence for a reasonable jury to find that this consideration weighs in their favor.

C. Legal Error

Defendants contend that this Court erred in undergoing a "lead compound," or alternatively "reference composition" analysis, in the Opinion filed September 30, 2011 (ECF No. 378). The Court typically engages in such analysis as an initial step in determining the obviousness issue insofar as inquiring a person of ordinary skill in the art would start to develop the claimed invention. The analysis unearths similarities between the claimed invention and the prior art. Defendants allege that this analysis was misguided and unnecessary since claim three does not present a new compound.

Plaintiffs appropriately note, and this Court agrees, that the "lead compound" analysis is "in essence no different than an analysis under the Graham factors . . ." (Pl.'s Opp'n 25). Indeed, this Court properly sought to unearth similarities between the claimed invention and the prior art in light of the issue of obviousness. Defendants' argument fails for reasons similar to the foregoing arguments in that recognizing a combination included by claim three, that is also included in the prior art, does not in and of itself render claim three obvious. Rather, Plaintiffs note a holding from the Patent Appeals Court stating that the "closest" combination in the prior art is sufficient proof regarding the prima facie case of obviousness. See Appl. of Boesch, 617

[5]Plaintiffs contend that rather than testing formulations and inadvertently or otherwise ending up with a drug strikingly similar to Tarka®, Glenmark intentionally copied the drug. Plaintiffs support this statement with evidence that Defendants filed an ANDA and wanted to produce a generic version of the drug. (Pl.'s Opp'n 22).

F.2d 272, 276 (C.C.P.A. 1980). Defendants' characterization of claim three as merely a "combination" of prior art elements fails to recognize the specific values that were ascribed to the elements involved in the combination. See supra Part III. The determination and presentation of those specific values in the claim, as presented by Plaintiff, constitute sufficient evidence of nonobviousness.

IV. CONCLUSION

Jury used the correct legal analysis, and the jury's conclusion was supported by sufficient evidence. Therefore, this Court hereby **denies** Defendant's renewed motion for judgment as a matter of law.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: May 30, 2012
Original: Clerk's Office
cc: All Counsel of Record
The Honorable J. A. Dickson, U.S.M.J.
File